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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,000	05/16/2005	Masakazu Hatano	05318/HG	1933

1933 7590 06/21/2010

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	**PAPER NUMBER**
1612	

MAIL DATE	DELIVERY MODE
06/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,000	HATANO ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-12* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed March 23, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

a. Claim 1 has been amended.

b. Claim 2, 4, 13 has been cancelled.

2. Claims 1, 5-12 are pending in the case.

3. Claim 1 is present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

Response to Arguments

6. Claims 1-2, 4, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azuma et al. (WO 00/09162).

Claim 2, 4, 13 are cancelled, the rejection is moot.

Applicant's arguments filed 3/23/2010 have been fully considered but they are not persuasive. Applicant argues that Azuma does not teach or suggest a Rho kinase inhibitor and another anti-glaucoma agent. This is not accurate or persuasive as Azuma teaches the Rho kinase inhibitors for glaucoma and teaches them to be useful alone or in combination with other compounds for this purpose (see Col. 2 line 25-28, Col. 7 line 1-58, Col. 8 line 50-58, Col. 9 line 4-6).

Applicant also asserts that Azuma does not teach combination therapy as useful for glaucoma which as addressed above, is neither accurate nor persuasive as Azuma does teach combination therapy (combination of drugs e.g. Col. 9 line 4-6). Applicant asserts that Azuma addresses that timolol is limited due to its side effects and one of ordinary skill would view timolol to be undesirable as an agent for treating glaucoma which is not persuasive and not an accurate presentation of the reference. Azuma teaches that B-adrenalin blocker such as timolol are widely used because they lower intraocular pressure without acting on pupils which is contrary to Applicant's assertion that one of skill in the art would view timolol as undesirable as the drug is widely use verses rarely used for the condition being addressed. As common with any medication, Azuma addresses that it has side effects such as dry eye and bradycardia where patient with the symptoms are not applied to patients with these symptoms which is understood in the art as one does not give sugar to a diabetic, but can be given to those without those particular conditions as it is effective which is why as taught by Azuma, it is a widely used glaucoma treatment (Col. 1 line 39-41). As a result, the combination of two known drugs each known for the same purpose, to form third composition that is to be used for very same purpose is obvious as Azuma teaches combining more than one compound for the composition.

In regards to Applicant's assertion of synergism for (R)- (+)-N- (1H-pyrrolo [2,3-b] pyridin- 4-yl)-4- (1-aminoethyl)benzamide (Y-39983) and timolol, it has been fully considered but not persuasive. The comparative is not commensurate in scope with the claims.

a. The presentation is directed to the future intended use of a composition which does not have patentable weight in a composition claim.

b. The comparative is only with a single concentration of 0.1% (R)- (+)-N- (1H-pyrrolo [2,3-b] pyridin- 4-yl)-4- (1-aminoethyl)benzamide (Y-39983) and 0.25% timolol, wherein the claims do not have any concentrations and a single point concentration is not reflective of a claim with no concentration points or ranges.

c. Applicant asserts synergism but the amount for the IOP reduction at hour 2 is additive (4.9 and 5.5=0.6 difference)which is not synergistic. It is noted that any arguments for a distribution of IOP is to future intended use which as addressed above, does not have patentable weight in a composition claim verses a method of treatment claim.

d. The comparative is not reflective of the claim which is to a composition/agent comprising the (R)- (+)-N- (1H-pyrrolo [2,3-b] pyridin- 4-yl)-4- (1-aminoethyl)benzamide (Y-39983) and timolol which is exemplified as an ophthalmic solution in specification (e.g. paragraph 31 of the U.S. Pat. Pub.). The comparative is described in the specification (paragraph 36-38) where the (R)- (+)-N- (1H-pyrrolo [2,3-b] pyridin- 4-yl)-4- (1-aminoethyl)benzamide (Y-39983) was given separately from the timolol, not together as in a single composition as recited in the claims and described in the specification with the ophthalmic solution. *Y-39983 was given first, then the timolol after about five minutes after, where there are two compositions- not one, given sequentially(paragraph 37).*

This is not reflective of the claims which is to a single composition/agent and exemplified in the ophthalmic solution of the specification.

e. The specification also states that it is impossible to instill the B-blocker solution (timolol) at the same time as the Rho kinase inhibitor solution wherein it was done sequentially (paragraph 37). This is confusing because if the two solutions could not be administered together, how does one deliver the composition that has both actives and why was a composition containing both actives not utilized in the comparative? *As a result, the comparative is not reflective of the claim as written as it utilizes two compositions/agents (each active in its own composition) and not a single composition/agent comprising both the (R)- (+)-N- (1H-pyrrolo [2,3-b] pyridin- 4-yl)-4- (1-aminoethyl)benzamide (Y-39983) and timolol as recited by the claim.*

Accordingly, the rejection is maintained.

Conclusion

7. Claim 1 is rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/

Examiner, Art Unit 1612
/Zohreh A Fay/
Primary Examiner, Art Unit 1612